



NDA 021158/S-022

SUPPLEMENT APPROVAL

Cornerstone Therapeutics, Inc.
Attention: Ashlie Adams, M.S.
Manager, Regulatory Affairs
1255 Crescent Green Drive, Suite 250
Cary, NC 27518

Dear Ms. Adams:

Please refer to your Supplemental New Drug Application (sNDA) dated July 26, 2013, received July 29, 2013, submitted under section 505(b) the Federal Food, Drug, and Cosmetic Act (FDCA) for FACTIVE (gemifloxacin mesylate) Tablet, 320 mg.

We also refer to our letter dated June 27, 2013, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for systemic fluoroquinolone antibacterial class. This information pertains to the risk of irreversible peripheral neuropathy.

This "Prior Approval" supplemental new drug application provides for safety labeling changes to the **WARNINGS** Section, **Peripheral Neuropathy** subsection, **PRECAUTIONS**, Section, **Information for Patients** subsection, **ADVERSE REACTIONS** Section, **Postmarketing Adverse Reactions** subsection, and **MEDICATION GUIDE** (Under "**What are the possible side effects of FACTIVE?**"), consistent with our June 27, 2013, letter.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text with the revision listed below.

Delete (b) (4) from the **ADVERSE REACTIONS Section, Post-marketing Adverse Reactions subsection**.

We note that your July 26, 2013, submission includes final printed labeling (FPL) for package insert and Medication Guide. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert, Medication Guide), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eList may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>”

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that include the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Susmita Samanta, Safety Regulatory Project Manager, at (301) 796-0803.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, M.D., M.P.H.
Acting Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):

Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SUMATHI NAMBIAR
08/14/2013